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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,232	04/10/2000	YASUO KONISHI	2139-11US-FC	1386

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OGILVY RENAULT
1981 MCGILL COLLEGE AVENUE
SUITE 1600
MONTREAL, QC H3A2Y3
CANADA

EXAMINER	
LIU, SAMUEL W	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/529,232	KONISHI ET AL.	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☒ Claim(s) *1 and 3-4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3/28/03* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants' amendment as to insertion of the sequence listing at the end of the specification has been entered. Claims 1-14 are pending.

Election/Restrictions

Applicants' election (filed 22 August 2002) of Group XXIV, claims 1-14 directed to Sequence 24 of SEQ ID NO:3, with traverse is acknowledged. The Traversal is on the ground(s) that there is a unity of invention between those Groups I – XXIV as read in the structure of Formula I (see page 1) and it would not impose a serious burden to the Examiner to examine all Groups (see page 2). The Applicant's traversal has been under due consideration; and, Groups I through XXIV are rejoined upon due reconsideration as the sequences of the groups are structurally related.

Therefore, the elected claims 1-14 with the Sequence Nos. 1-24 of SEQ ID NO:3 are under examination to the extent that they are drawn to the elected invention.

Object to Oath

The oath or declaration of this application is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because the signature for the full name of each inventor (family name and at least one given name together with any initial) has been unclearly set forth (see "Inventor's Signature" section of the declaration for Yasuo Konishi and Jacek Slon, page 1-2).

Specification/Claims Objections

The disclosure is objected to because of the following informalities:

In page 1, line 28, between "wherein" and "Arg-X" should insert "the linkage between residues Arg and X in".

In page 2, line 30, "Gp Iib/IIIa" should be changed to "glycoprotein IIb-IIIa complex (Gp Iib/IIIa)".

In page 8, line 33, "250-300-fold" should be changed to "250 – 300 fold".

In claim 1, "an S subsite" should be changed to "a S subsite".

In claims 3 and 4, "Cha represent" should be changed to "Cha represents".

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. §101 states:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 7 and 8 rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112, the second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation "an S subsite" (line 50) because "S subsite" has not been defined in the specification, and it is unclear as to whether or not "S" refers to part of "AS" or serine binding site, or has a meaning, e.g., a substrate binding site. See also "S' subsite" (lines 8-9). The dependent claims are also rejected.

Claim 2 recites the limitation "As". There is insufficient antecedent basis for this limitation in the claim 1 from which claim 2 depends. The dependent claims are also rejected.

Claim 5 recites the limitations "said compound" and "the compound". There is insufficient antecedent basis for this limitation in the claim 1 from which claim 6 depends. See also claim 6.

Claims 9 and 10 recite the limitation "a compound". There is insufficient antecedent basis for this limitation in the claim 1 from which claims 9 and 10 depend.

Claims 7 and 8 provide for the use of a compound defined in claim 1; but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/ process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 112, the first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating vascular diseases comprising administering to the patient the peptides of SEQ ID NO:3, does not reasonably provide enablement for a method of preventing vascular diseases comprising the same. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The current application disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The present application does not provide factual indicia including clinical evidence, guidance as to preventing vascular disease comprising administering to a patient the claimed composition since the pathological mechanism as well as administering route for preventing a disease state differs from that for treatment thereof. Therefore, the claim language "prevention"

would render the claims so broad that the scope of claims is outside the bounds of the enablement and would have resulted in the necessity of undue experimentation.

The general knowledge and level of skilled in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe how the claimed peptide for thrombin inhibition has same or similar pharmaceutical efficacy in both treatment and prophylaxis. Thus, one of skill in the art is required to perform undue experimentation to conduct pharmacological study and prevention trail for vascular disease using the claimed peptide.

In the absence of experimental data for vascular disease prevention, the results of clinical investigation with respect to cytotoxicity of the claimed thrombin inhibitor to the patient, it would take undue trials and errors to practice the claimed invention (it is of note that dosage for prophylaxis may quite differ from that for treatment). The quantity of experimentation thus would be large and unpredictable.

In re Fisher, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. The method of prophylaxis with administering to the mammal is species-dependent or/and age-dependent. Note that mammal encompass a large number of species of animal including human being. Also, it is not clear that the same dosage or/and administering route to one species would applied to other species of mammal without apparent pharmacological toxicity. Therefore, it is unclear that the skilled artisan could predict the efficacy of the preventive use the same to a mammal. The invention is therefore unpredictable with respect to the recitation "prevention of vascular diseases of a mammal".

In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703 308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

Samuel W. Liu, Ph.D.

July 30, 2003

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER